

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT


(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L/AH66/VA/15	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 02/04207	International filing date (day/month/year) 12.04.2002	Priority date (day/month/year)
International Patent Classification (IPC) or both national classification and IPC A61K9/16		
Applicant CAMPINA NEDERLAND HOLDING B.V.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
  - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  22.09.2003	Date of completion of this report  01.09.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Uhl, M  Telephone No. +49 89 2399-8654



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 02/04207**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-9 as originally filed

**Claims, Numbers**

1-26 received on 17.06.2004 with letter of 17.06.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
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International application No. PCT/EP 02/04207

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-26
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-26
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document/s/:

D1: EP-750492

Claim 1 of the present application is now omitting the antrone reaction which was seen as unusual if used in connection with a twin stage impinger. All claims are now clear and the international search report is regarded to cover all the now claimed subject matter.

The document D1 is regarded as remaining the pertinent prior art for the subject-matter of the present invention and discloses primary particles from 1-15 $\mu$ m with particles (=pellets) made thereof in dimensions of 50-1000 $\mu$ m (preferred 150-1000 $\mu$ m, most preferred 200-800 $\mu$ m). These pellets are said to be stable enough to be packaged, transported or stored but will be disrupted into independent primary particles upon egress into the turbulent airstream within the inhaler. The excipient used is lactose and the medicaments transported with such pharmaceutical form are those usually formulated in inhalation therapy (see §9 of D1). The wet preparation is disclosed in col.4, l.16-31 of D1 with an implicit final drying step before contacting the pellets with medicament (see §16, where it is mentioned that the pellets should be stored under unhydrous conditions which is equivalent to drying; it should be kept in such a way that free water is less than 1%). As D1 covers the whole technology necessary to produce said pellets from primary particles, even a choice of another excipient than lactose seems not to be inventive over this prior art as being considered as an arbitrary choice out of the list of normal substances at hand for the skilled person without exerting an inventive activity. The only difference to this prior art product is the characterisation by specifying the amount of excipient which reaches the stage 2 of a twin stage impinger. Such characterisation renders subject matter of claims 1-26 novel over the cited prior art. However the procedural steps which shall lead to the product which falls under the definition of the parameter seem to be identical to those in D1 which leads to the following objection : subject matter of claims 1-26 seems not to be inventive in view of D1 = EP750492 (citations see international search report) as the definition by a parameter reached in the twin stage impinger is seen as an arbitrary choice without exerting an inventive activity. The different ways of drying the granules or the nature of the basic substance like lactose is also seen as a choice within different possibilities at hand for the skilled person without exerting an inventive activity.